MINUTES FROM THE EPA/SCIENCE ADVISORY BOARD
Arsenic Rule Benefits Review Panel
July 19-20, 2001

PURPOSE: The Arsenic Rule Benefits Review Panel met to discuss EPA's Economic Analysis supporting the National Primary Drinking Water Standard for Arsenic. The meeting was announced in the Federal Register at FR Vol. 66, No. 127, Pages 34924-34928 (July 2, 2001) (see Attachment A). An agenda is included as Attachment B.

LOCATION: The meeting was held at the Ronald Reagan International Trade Center Conference Center, 1300 Pennsylvania Ave., NW, Washington, DC.

PARTICIPANTS: The following participated in this meeting: Drs. Maureen Cropper, Richard Bull, A. Myrick Freeman, Michael Hanemann, Dale Hattis, Irva Hertz-Picciotto (day two via telephone conference), and V. Kerry Smith. A committee roster is included as Attachment C. EPA Staff and persons from the public who attended the meeting are indicated on the sign-in sheets (Attachment D).

MEETING SUMMARY: A summary of the committee's activities follows.

1. Welcome and Introductory Remarks; Dr. Maureen Cropper, The World Bank, (8:30 am)

Dr. Cropper called the meeting to order and welcomed the panelists and observers. She noted that EPA's charge (Attachment E) asks the SAB to advise on whether it believes EPA's benefits analysis components, approach and estimates are reasonable and appropriate and also asks for advice on improving the approach.

2. Welcome and Introductions, Mr. Thomas Miller, Designated Federal Officer for the Panel

Mr. Miller also welcomed the panelists and public and thanked the panelists for their willingness to serve on such short notice. The report to the Administrator is due at the end of August, making it imperative that the report go to the SAB Executive Committee around the second week of August.

Mr. Miller noted that the Science Advisory Board is charged with providing independent expert scientific advice to the EPA Administrator and that members and consultants are brought into the SAB process as Special Government Employees (SGEs). As such they are subject to certain Conflict of Interest (COI) and ethics regulations and guidelines which preclude their participating in activities which might significantly affect their financial interests. In addition, the Federal Advisory Committee Act requires advisory panels established by the SAB are required to reflect balance in the technical views held by the panel members. Mr. Miller stated that the Administrator makes her decisions based on many different types of input and analysis, only one of which is the advice of advisory panels like the SAB.

Mr. Miller stated that based staff's evaluation of written information provided earlier by the members, discussions with panelists, and consultation with Agency Ethics Officials that there is no conflict of interest present in the panelists conducting this review. He also noted that considering appearances of conflict, panel balance, and sharing information on who we are with those of the public who are interested in these proceedings is part of SAB's practice. In this regard, the SAB asks its panel members to note for the record information on their past experience and interest in any issue on the day's agenda so that all present might learn more about the background they bring to the Panel's activities. He asked that the members introduce themselves and indicate their institutional affiliation and any other information they feel to be of interest regarding their research or professional activities that might be relevant to the day's agenda.

Information on Panel Members below is taken from the biographical sketches made available before and at the meeting as well as comments made by the Panelists during their introductions. Additional detail on this topic and other portions of the meeting can be found in the Transcripts made for the meeting which are available on the SAB website at www.epa.gov/sab/.

a) Dr. Maureen L. Cropper, (Chair) received her Ph.D. in Economics from Cornell University. and now serves as the Principal Economist in the Policy Research Department of The World Bank and Professor of Economics at the University of Maryland. Dr. Cropper's research areas include the evaluation of nonmarket benefits, especially health benefits. Specific projects have addressed topics such as valuing the health benefits of environmental programs and the study of the political economy of environmental regulation. Dr. Cropper has served as the Chair of the EPA SAB Advisory Council on Clean Air Compliance Analysis and as a member of SAB Environmental Economics Advisory Committee. She specifically noted one research project on deforestation in Thailand for NASA and that all her other research has been conducted for and supported by The World Bank.

b) Dr. A. Myrick Freeman, III, received his Ph.D. in Economics from the University of Washington. He is now the William D. Shipman Research Professor of Economics, Bowdoin College Economics Department. Dr. Freeman's principal research interests are in the areas of the economics of environmental policy, benefit-cost analysis, and nonmarket valuation. Much of that work focused on the development of models and techniques for estimating the welfare effects of environmental changes such as the benefits of controlling pollution and the damage to natural resources from releases of chemicals into the environment. He has authored or co-authored eight books including *The Economics of Environmental Policy* (with Robert Haveman and Allen Kneese), *The Benefits of Environmental Improvement: Theory and Practice*; *Air and Water Pollution Control: A Benefit-Cost Assessment*; and *The Measurement of Environmental and Resource Values: Theory and Methods.* Dr. Freeman has served on the EPA SAB Environmental Economics Advisory Committee, the SAB Advisory Council on Clean Air Compliance Analysis, and the SAB Clean Air Scientific Advisory Committee. Dr. Freeman also served on the National Academy of Sciences'(NAS) Panel on Effects of Ambient Environmental Quality, the NAS Committee on Assessment of PCBs in the Environment, and the NAS Workshop on Land, Sea, and Air Options for the Disposal of Industrial and Domestic Wastes. Dr. Freeman noted that his EEAC service included participation on the panel that reviewed the EPA economic analysis guidelines and the EPA white paper on valuing fatal cancer risk reductions. He stated that his daughter [not a dependent] is a partner of Hunton and Wlliams, a law firm having clients who are affected by the arsenic rule, though she is not involved with the issues and they have not nor will they discuss it.

c) Dr. Richard J. Bull, received his Ph.D. in Pharmacology from the University of California, San Francisco. He is an adjunct Professor of Pharmacology and Toxicology at the Washington State University Department of Pharmacology and Toxicology and the principal of MoBull Consulting, Inc. His research interest has primarily been in toxicology and focuses on mechanisms that produce carcinogenic effects of some by-products of drinking water disinfection and halogenated solvents. Dr. Bull served in a number of research positions as a Public Health Service Officer at the US EPA Health Effects Research Laboratory, retiring in 1984 as the Director of the Toxicology and Microbiology Division of the laboratory. He also served as Senior Staff Scientist at the Batelle Pacific Northwest Laboratory from 1994 - 2000. Dr. Bull served as the Chair of the EPA SAB Drinking Water Committee from 1996 through 2000 and currently is a member of the SAB Research Strategies Advisory Committee. Dr. Bull Chaired the National Research Council (NRC) Committee on Copper in Drinking Water and the NRC Subcommittee on Water Quality in Space Station Freedom. He also served on the NRC Subcommittee on Drinking Water Disinfectants, the NRC Committee on Recycling, Reuse, and Conservation of Water, the NRC Committee on National Water Quality Assessment Program, and the NRC Committee on the Viability of Augmenting Potable Water Supplies with Reclaimed Water. Dr. Bull noted that he had been contacted by a Natural Resources News Service reporter about the nature of his consulting firm's clients. He read from, and introduced into the meeting record, a note that he sent to NRNS on July 3, 2001, discussing his clients and the nature of his work for them (see Attachment F). He also noted that he was Chair of the SAB Drinking Water Committee when it reviewed parts of EPA's proposed arsenic in drinking water

proposed rule.

d) Dr. W. Michael Hanemann, received his Ph.D. in Economics from Harvard University. He is the Chancellor's Professor in the Department of Agricultural and Resource Economics and the Goldman School of Public Policy at the University of California, Berkeley. Dr. Hanemann's research focuses on water resource economics primarily in the area of water supply economics and wastewater disposal. His recent work has considered the economics of water supply and urban water demand . Dr. Hanemann has conducted research on various aspects of nonmarket valuation of water quality. Dr. Hanemann is a member of the EPA SAB Environmental Economics Advisory Committee and has served on the National Research Council's Committee to Review the Glen Canyon Environmental Studies Program and the NRC Committee on Wolf and Bear Control in Alaska. He has also served on a number of expert panels on water resource issues for entities at the local water district and the state level. Dr. Hanemann noted that he has done work on the economics of water supply and sewerage for many years and has consulted with a number of utilities.

e) Dr. Irva Hertz-Picciotto, received her Ph.D. in Epidemiology from the University of California, Berkeley. She is a Professor of Epidemiology at the University of North Carolina School of Public Health. Her research interests include epidemiologic methods, environmental exposures, and reproductive health outcomes. Specifically, Dr. Hertz-Picciotto has worked on issues such as survival analysis in studies of adverse pregnancy outcomes, the healthy worker survivor effect, assessment of interactions between two or more exposures, the integration of epidemiologic data in the quantitative assessment of risk from environmental hazards, and issues related to timing of exposure during pregnancy. She has also conducted arsenic specific research. Dr. Hertz-Picciotto was Chair of the National Academy of Sciences/Institute of Medicine Committee to Review the Health Effects in Vietnam Veterans of Exposure to Herbicides. She has served on a number of advisory committees at the state and national level including panels for the National Cancer Institute and the National Institutes of Environmental Health Sciences. She noted her work in food safety issues in the European community for ILSI and hazard assessment methods. She has received funding from a variety of sources including, HEI, CDC, NIH, EPA, AWWARF (reproductive outcomes for DBPs) and California EPA. She has conducted some arsenic specific research and conducted in a past job for the state of California, a risk assessment of arsenic in the air.

f) Dr. V. Kerry Smith, received his Ph.D. in Economics from Rutgers University. He is the University Distinguished Professor in the Department of Agricultural and Resource Economics at the North Carolina State University and Director of the Center for Environmental Resource Economic Policy at NCSU. Dr. Smith's research interests include: non-market valuation of environmental resources, the role of public information in promoting private risk mitigation, environmental policy and induced technical change, non-point source pollution and nutrient policy. Dr. Smith has conducted research on the use of Monte Carlo analysis methods in econometrics and many other aspects of valuing the benefits of environmental regulation. He has served on the EPA SAB Environmental Economics and Policy Committee and is now a member of the SAB Advisory Council on Clean Air Compliance Analysis. He also serves on EPA's Children's Health Protection Advisory Committee. He is also a University Fellow with Resources for the Future. Dr. Smith was Chair of the National Academy of Sciences Committee on Sanitary and Phytosanitary Standards and International Trade. Dr. Smith also noted that he was a past Co-Chairman of the SAB's Environmental Economics Advisory Committee. He has conducted research smoking for the Robert Wood Johnson Foundation and has done research for DOE and EPA.

g) Dr. Dale B. Hattis, received his Ph.D. in Genetics from Stanford University. He is a Research Professor in the Clark University Center for Technology, Environment, and Development and has over twenty years experience in the development and application of methodologies to assess the health, ecological, and economic impacts of regulatory actions. His research interests include the development of methods to incorporate interindividual variability data into risk assessments for both cancer and non-cancer endpoints; quantitative risk assessments for reproductive effects of ethoxyethanol, neurological effects of acrylamide, chronic lung function impairment from coal dust; and the analysis of uncertainties in pharmacokinetic modeling for perchloroethylene. He has experience in the use of Monte

Carlo simulation analysis of uncertainties in carcinogenic risks for air and drinking water pollutants. Dr. Hattis was a member of National Academy of Sciences/Institute of Medicine Committee on Evaluation of the Safety of Fishery Products, the NRC Committee on Neurotoxicity and Risk Assessment, and is a member of the NRC Committee on Estimating the Health Risk Reduction Benefits of Proposed Air Pollution Regulations. He is also a member of the Massachusetts Department of Environmental Protection/ Department of Public Health Advisory Committee on Health Effects. Dr. Hattis noted that he is a biologist and has focused his efforts on quantifying health effects. Most of his work is for EPA, but he also noted work for environmental groups and OSHA. He has a specific interest in his work on interindividual variability in human responses to toxicants.

3. Administrator's Letter to the Panel Chair

Mr. Miller read into the record a letter delivered to the Panel Chair at the beginning of the meeting about "...concerns...raised regarding the panel's composition, and in particular, it has been suggested by NRDC that the panel is not well 'balanced.'" The Administrator wished to "...confirm that all interested parties will have ample opportunity to present their views to the panel on July 19 and 20, and will be allowed to submit written comments" and that "...the Panel will weigh and consider all of the evidence, testimony and various viewpoints presented as part of this public process in formulating its report." (See Attachment G)

Mr. Miller noted the afternoon's public comment period for which two persons have registered. He also noted that it was common SAB practice to allow those who did not preregister, but who identify themselves during the meeting, to speak during the public period if time is available. He asked any interested parties to inform him if they wished to speak at that time. He also noted the SAB convention of accepting written comments during its meetings, and when time to prepare has been short, of accepting written comments for a time after the meeting. Mr. Miller noted that 10 calendar days would be available after this meeting for accepting such written comments (July 31, 2001).

4. Overview of the Rule-making and EPA's Benefits Analysis; Mr. Ephraim King; (9:00 am)

Mr King stated that the Panel was principally being asked to look at the underlying methodology used by EPA in its benefits analysis. These underlying issues are also relevant and applicable to other rule making activities. He discussed the principal statutory requirements relevant to the arsenic rule (statutory deadlines, conduct of health risk reduction and cost analysis, use of best science available, NAS consultation, MCL setting vs. MCLG, and maximization of health risk reduction at a level justified by the benefits) and the process for setting drinking water standards. He noted that based on the data available, the MCLG was set at 0. The feasible level was judged to be 3 ppb, however, the MCL chosen for the final rule, 10 ppb, was the level at which the benefits were judged to be justified by the costs. EPA has exercised the Administrator's discretion to move off the feasible level which is allowed under SDWA (see Attachment H).

Mr. King discussed the additional procedural steps being taken to update the arsenic health analysis (NRC), cost analysis (NDWAC) and benefits analysis (SAB)and noted the overlap between the SAB charge and that of the NRC. The question for the SAB Panel is whether EPA's approach was reasonable and appropriate and whether the Panel has suggestions that can improve EPA's earlier analysis. He stated that all three reports will be received at the end of August and placed on the Office of Water website for immediate public availability. A fall FR notice will request comment on the reports as well as other inputs and offer a tentative decision from the Administrator. The final arsenic rule is due in February 2002; however, the implementation date will remain as previously published, 2006.

Mr. King stated that the arsenic analysis began with the Taiwanese data discussed in the rule and applied dose-response models from Morales et al., (2000) to estimate bladder and lung cancer

risks. Final risk estimates for alternative MCLs incorporated water consumption patterns and arsenic occurrence distributions. From this, EPA calculated the expected cancer cases for the various MCLs and fatalities were monetized using a VSL of $6.1M each and nonfatal cases monitized using the $600K chronic bronchitis derived value.

Non-quantified benefits associated with other cancers and noncancer health effects were merely listed in the economic analysis. Differing levels of confidence exist for individual listed effects. In addition, if high confidence exists for a relationship between arsenic and the effect, the percentage of the national incidence of the disease in question that can be associated with arsenic becomes important. EPA may not be able to calculate the benefits because of the latter factor even though it may have a higher confidence in the relationship between the endpoint and arsenic itself.

Mr. King noted that a number of factors were considered in a sensitivity analysis instead of the primary analysis. For example, latency is considered to be so poorly understood that it was judged to be inappropriate to include an adjustment to the benefits flow (via discounting) in the primary analysis (in contrast to previous SAB advice which stated that discounting should be done in the primary analysis).

In sum, the EPA needs advice from the Panel on:

- how total and incremental costs and benefits should be addressed for the regulatory alternatives to ensure appropriate consideration and communications (is analysis of total as well as incremental costs/benefits appropriate_;
- how latency should be addressed in the benefits estimates in the face of uncertainty in the underlying data (is further consideration of latency appropriate);
- whether exposure reduction should be evaluated as a separate benefits category or in conjunction with morbidity/mortality;
- how other health endpoints should be further addressed in the analysis in the face of limited data; and
- how uncertainty should be addressed in a benefits analysis

Mr. Frank Letkiewitz, Cadmus Group, presented additional information on how the Agency calculated the cancer cases associated with predicted preregulatory and a postregulatory arsenic levels. (See Attachment I for topics covered).

The Panel and EPA representatives discussed the relationship between arsenic exposure and the probability of developing cancer. Dr. Cropper constructed a function to represent the relationship between arsenic effects over time and asked if this was well known in the health community. EPA representatives noted that their estimates were derived from one of eleven risk models in the Morales et al. paper which shows risk increasing quadratically with age. Dr. Hattis complimented the Morales analysis and suggested that one could take a couple of additional analytical steps and derive the function contingent on a multistage model for U.S. populations based on U.S. morbidity and mortality data. Panelists noted the need to be consistent in the way one addresses potency throughout the analysis.

<u>Issues Mr. King would like feedback on include</u>:

- Is the chronic bronchitis valuation measure the best model to use for computing non fatal cancer value?

- For non-quantified benefits, what level of confidence exists that exposure to arsenic leads to the endpoint. If the relationship is thought to be strong, what percent of the

national incidence for each disease/condition could be attributed to arsenic? Can we at least say that arsenic would be a major or a minor contributor to the endpoint? Would the information be useful to a decision maker?

- It would be good if the Panel could help EPA in its determination of the best latency scenarios/periods to use in its analysis (possible area of NRC overlap). For the rule, the 5, 10 and 20 year latency referred to the interval from exposure to mortality. Further, information that would help EPA understand the different latency scenarios with respect to the kind of endpoint expected would be helpful. Also more on the scenarios to evaluate to have a complete picture, e.g., steady levels of exposure over a lifetime vs. exposure at one level for a period followed by a decreased level at some point, or the period from exposure to occurrence or the period between exposure and when the benefits of reduced exposure begin to occur in the population (this was considered a "lag" instead of latency by some Panelists). Is this relevant to a decision maker for arsenic?

- Would the panel think that consideration of averting behavior is relevant to the arsenic situation in terms of getting some sense of the significance of the benefits of unquantified endpoints?

Comments and questions from Panel members included:

- For non-quantified benefits, individuals may exhibit averting behaviors (e.g., filters, bottled water) to avoid the risk -- that is, information can helps them mitigate that exposure. So one has to consider both behavior and exposure together. Has this been considered in EPA's efforts?

- The approach to weighting and calculating averages was questioned because the method used might obscure the fact that in some communities you may have disproportionately high numbers of very old or very young persons and the outcome from exposure would likely differ between such communities.

- With respect to the effects evaluated, did EPA consider exposure during childhood that would lead to an effect later even if exposure is decreased along the way? Is risk calculated separately for different age groups?

- Regarding Non-cancer effects, the morbidity effects for some may be as important as mortality itself in evaluating the overall health burden, and therefore the benefits of reducing arsenic levels. Not all the listed effects are independent from one another. Is there a breakout in the record about the doses where the effects occur and the type of data that the suggestion of a risk is based upon (animal data, human data, e.g.)?

- Cancer models are problematic and have no time dimension – they assume a lifetime exposure. You end up relating some average exposure to some risk level. The relevant dimension you would like to know is the conditional probability of death at each age as a function of exposure. Is the relationship known?

- In arsenic, the exposure expected in the US is low in contrast to high doses that we see in some other countries or in some other risk situations (e.g., smoking).

- There are important interactions between issues being addressed by the group doing the

cost analysis and the issues to be addressed by this SAB Panel and a mechanism for dialogue between the two would be good.

- There is a disconnect between the way costs and benefits are presented which has uneven implications for how one views the uncertainty associated with the specific analyses. Costs are given to four significant figures which can imply low uncertainty levels –which probably is not the case --while the benefits are treated much differently and uncertainty is emphasized. There is a need for this Panel to have information on the uncertainty analysis done on the cost side.

10:35 am Break

5. Characterization of U.S. Population Exposure in the Analysis (10:55 am)

Dr. Bull briefly discussed how EPA had characterized exposure in its assessment of risk. He noted the basic report from EPA that provides information on drinking water consumption for various components of the U.S. population (male, female, age groups, geographic areas, tap water, other water) (see Attachment J- "Estimated Per Capita Water Ingestion in the United States"). Little additional information on arsenic exposure is available in the EPA analysis beyond exposure for various system size categories. He discussed the weakness in the exposure data in the Taiwanese study that is used as the basis for dose-response in EPA's risk estimates. Dr. Bull noted that he had attempted a simple cost vs benefit display for systems of various sizes (see Attachment K).

An EPA representative noted that occurrence information used in the EPA analysis is from an occurrence assessment – "Arsenic Occurrence in Public Drinking Water Supplies" that presents a distribution of occurrence for different system types, size and levels (see Attachment L).

Other Panelist Comments:

- Having information on the number of exposed, and how much exposure they receive, for each system size would be useful

- Improved exposure data may be available in some of the more recent epidemiology studies conducted in other parts of the world (Northeastern Taiwan, a Chilean study by Ferraccio)

- The occurrence information does not give the reader an idea of where arsenic actually occurs; a real regional dissagregation at least would be better.

- It is important in Monte Carlo analyses for others to be able to reproduce the analysis from information provided – we could not do so.

- Members wondered about the variability of arsenic concentration over time within a specific source (one EPA representative noted concentrations can vary substantially over space and time while another noted that it depends on whether it is ground or surface water and what the arsenic source is, e.g., non-point sources would be variable while weathering of bedrock would be rather constant).

- Members discussed the assumption of system's targeting 80% of the MCL promulgated as the level to achieve in order to have a margin for comfort and the relation of that choice to the benefits estimate (possible biasing element).

- Members were interested in the food contribution of arsenic in the Taiwan study.

- The issue of whether the distribution of system sizes where arsenic is highest is the same as the distribution nationally was discussed. If different, the national estimate may not predict well for the region and a regional analysis might be needed. The BC tradeoff may be more questionable as one goes down in system size.

- A transparent description of how one got the information in Exhibit E-1 and E-2 would be helpful (a more fine tuned version of this section).

Lunch 12:35 - 1:35

6. Quantification of Cancer Dose-Response

Charge Question 1 (Health Perspective): *How should **latency** be addressed in the benefits estimates when existing literature does not provide specific quantitative estimates of latency periods associated with exposure to arsenic in drinking water?*

Dr. Hattis opened the discussion by noting that the problem can be approached by developing a classical Armitage-Dahl or multistage models of the morbidity and mortality of various cancers in the U.S. population and then exploring mathematically the expected distributions of times to diagnosis and times to death for various cancers, making different causal assumptions about which stages are affected in these multistage models. He noted further that it should be done by reference to existing U.S. data (he referred to the 1994-98 SEER data).

Dr. Hattis further discussed the genesis of cancer in stages and the notion that the multistage model was suggested by the regular pattern of the log of the incidence of cancers versus the log of age up until quite high ages. He stated that the relationships can be derived from existing U.S. data for lung and bladder cancer. Once this is done you have the estimate of the number of stages and an estimate of the lag that represents the time difference on average between the birth of the first cancer cell and either clinical diagnosis or mortality. Dr. Hattis noted that from this a simple spread sheet model can be prepared showing the age dependency of development of cancer using some basic assumption about the number of eligible stem cells that have undergone various numbers of transitions. This spreadsheet of time on one axis and number of cells with different transitions on the other can give a time dependency of possible change in exposure on morbidity and mortality (this is an approximate form of the multistage model). Multistage possibilities should be a part of the analysis or at least the sensitivity analysis.

Other Panel Comments

- the Moolgavkar model could be used as well

- Different cancer sites may have different lags (some epidemiology data suggest arsenic acting in a relatively late stage for occupational lung cancer based on inhalation exposure --Lubin; Brown and Day-- while other data for bladder cancer suggest an appreciable lag effect that would only happen if arsenic affected targets in earlier stages)

- The Ferraccio paper on drinking water exposure was raised as being of some use in

assessing the type of lag effect involved

- With respect to the graph shown by Mr. Letkiewitcz, is there enough data to alter that and if so how would we alter it? This affects the way we do the valuation estimates which are related to an avoided statistical death that happens at some instant. The risk change is multiplied by a VSL. So how do we use the latency information to change the value?

- The data in the graphs of Chen's study show some latency for mortality and one can overlay this with U.S. data for morbidity and mortality and get an idea of how the curve goes with exposure. It will not give you an idea of whether arsenic exposure at different life periods is more important than at others.

- A latency vocabulary is important. Three types appear to exist for this case. One, time from exposure to cancer/tumor (for those already at this point, the regulation will not change risk because the change has already occurred). Two, an existing cancer that is not yet observed and the time until it is manifest clinically (morbidity) is another latency period; and then the latency from time of cancer change to death. For valuation, the "time to cancer" latency indicates how rapidly cancer patterns declines after the new level. The second latency applies to the time interval for the discounting when a VSL is used. We can infer what these periods could be. These could be done however they have not been done yet and it will be challenging to do this and to appropriately express the uncertainties.

- The panel discussed the possibility of tailoring the benefits analysis to the age distribution of the population (profile) actually affected in a water system because not all endpoints would be relevant to certain age groups.

- Modeling exposures up to the point of death may produce a larger exposure estimate than that which actually led to the changes that induce the cancer. Whether calculating this exposure is relevant may be determined by whether the cancer is a late stage of an early stage cancer.

- While the latency estimates taken with these procedures are still subject to uncertainty, they are at least derived from information and not just pulled out of the air and as such, would have more credibility.

7. Characterization of Non-Quantified Endpoints

> **Charge Question 2 (Health Perspective)**: *How should **health endpoints (other than bladder and lung cancer)** be addressed in the analysis, when [existing] literature does not provide specific quantification, to ensure appropriate consideration by decision makers and the public?*

Dr. Hertz-Picciotto referred to her five-part table providing data on arsenic in relation to a number of as yet unquantified endpoints (see Attachment M). She noted that the information though extensive is but a start and it is neither comprehensive in terms of endpoints covered or studies included. Tables presented included those on human and animal morbidity studies for cardiovascular and metabolic endpoints (I and II), human mortality studies of cardiovascular and metabolic endpoints (III), human morbidity and mortality studies of non-malignant respiratory and neurologic endpoints (IV), and human reproductive studies (V).

These do not cover all on the EPA list but they do cover many of the main ones. Her emphasis was on endpoints where we have good studies and the weight of evidence seems to be good. She pointed out that these have been unquantified, but they are not unquantifiable. For some, she stated that the strength of evidence is in the same ball park as that for bladder and lung cancer. She also noted that occupational studies are usually done in more healthy individuals and their results do not show too much. The reason (better health vs lack of occurrence of effects) for this is not clear. Dr. Hertz-Picciotto then highlighted a number of the endpoints that she thought were particularly important (hypertension, peripheral vascular disease, non-malignant respiratory effects, neurological endpoints, reproductive studies). She noted that their seems to be good concordance in listings in the mortality vs the morbidity tables. More than just mortality should be evaluated. She suggested that a benchmark dose might be good to do for the studies in the table.

Other Panelist Comments:

- The health effects panelists agreed that more could be done.

- Members discussed the possible differences that exist in persons with respect to how they would respond to various arsenic levels and to other environmental factors (e.g. diet).

- Dr. Hattis noted a simple analysis he did on the Wu study that evaluated the overall excess cancer risk, at high doses, relative to the lung and bladder cancers (this is a public health or population aggregate analysis). One can also do the same for vascular diseases. Though not fully quantitative, the analysis does add some perspective to the available information for decision making. He also noted a "risk factor option' for addressing lower doses. He noted that those comfortable with his approach would now be a small group.

- Knowing the maximum ratio of those endpoints that we believe can be quantified, but which have not yet been, to the already quantified effects could be important to saying more on benefits (especially when going from high dose study situations to low dose environmental exposures). Why have we not done the evaluation for the other endpoints given the existence of these studies? It appeared to some that we do not have as straightforward method to do the quantification.

- Some wondered why cancers in the liver and kidney had not been calculated. They might not have been calculated because they were thought to only add a small amount to the overall benefits calculation. Even though they might only be a small percentage of the total effect, they would still add to the benefits (lack of experiences, lack of a policy-tested construct, etc.).

- Doing a benchmark dose is a possible way to do more. It would allow you to say at least how the concentration in water related to the benchmark (10x or 100x different).

- Valuation pushes on the cancer fatality endpoint because at $6.1 M per VSL it becomes a driver of the overall benefits. The mortality perspective would value five fatal outcomes as a product of cases times value per fatality. But a risk perspective, a large number at risk with a lower value per unit risk could also produce a large willingness-to-pay – it is not just cases avoided it can be number at risk All at risk gain from something done to decrease the risk.

– Further, for endpoints with very large totals of the U.S. population involved, even a smaller risk ratio (e.g., 1.2) could end up with a very large number of fatalities to put into a valuation analysis.

– The proportion of total cases in the U.S. which can be attributed to arsenic is important to the analysis.

– At least having an analysis along these lines would give some additional sense of what the bounds of the problem might be. That should be better than a mere list.

EPA Comments:

– The lower end case in the analysis considers all arsenic to come from drinking water. In reality, of the 55 micrograms per day ingested in the U.S., EPA only estimates that about 15 come from water (on an inorganic basis).

8. Valuation of Health Endpoints (3:10 pm)

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Charge Question 1 (Economic Perspective): *How should **latency** be addressed in the benefits estimates when existing literature does not provide specific quantitative estimates of latency periods associated with exposure to arsenic in drinking water?*

Dr. Cropper provided a brief introduction saying that her earlier comments on weighting in premature mortality valuation were intended to note that this metric counts a lot in the overall benefits calculation. However, the value does not reflect any difference in the mortality of one dying at age 40 or at age 75. In addition the chronic bronchitis figure for non-fatal cancers is strange given that there is an economics literature on what people would pay to reduce their risk of lymphoma, which though different is at least a form of cancer. In addition for other effects (stroke and heart attack) valuation is based on avoided medical costs and lost earnings in the Clean Air Act. This does not say that it must be done this way here, only that another agency program has done so.

Dr. Freeman noted that there are two factors in latency that are of interest. One is the rate of decline in the number of deaths over time after achievement of a new MCL (time to cancer lag) and the value of deaths avoided, the VSL. The first takes into account the interval between reduction in the cancer event, the cellular change that becomes cancer, and when it manifests itself as morbidity or mortality. For the latter, discounting is appropriate in the primary assessment (for morbidity and mortality) if latency can be quantified as the risk assessors here suggest is possible. The value of non-fatal cancers should also be accounted for.

Additional Panelist Comments:

– For a lower bound estimate, averting behavior may provide an estimate; it at least has a similarity in derivation to the wage-based $6.1 M VSL.

– The source of the $6.1 M VSL figure was discussed. This should be mentioned in the uncertainty analysis.

– Using the $6.1 M figure implies a level of certainty in the estimator that is not universally accepted.

- Lack of risk information is as much an impediment to calculating benefits as lack of economic information.

- There is difficulty in mapping from the list of physical effects in the analysis to economic measures for valuing. There is a need to close the gap. Pain and suffering are left out as well.

- One could make a judgment call about some unquantified endpoints in terms of how many times worse the endpoint is than some other thing we have a measure for, not a precise estimate. Possibly one could talk of relative disutility. Quality of well-being scores, Kaplan scores, have been used for respiratory morbidity impacts and one could see if that could be used here – notwithstanding the past comments on QALYs, this would still be better than saying something like bladder cancer is equivalent to chronic bronchitis.

- Past advice noted that the use of QALY's is still not ready for application to environmental issues.

- Cost-effectiveness analysis could be considered for analyzing the benefit of alternative MCLs. With different ways to measure morbidity value and mortality value one would have a problem in aggregating the different types of outputs (QALY, VSL).

EPA Comments:

- The chronic bronchitis number was used in the hope it would at least be a lower bound even though it is not as severe as lung or bladder cancer. It is also used here because it has been used in other rules and it at least gives some consistency with them.

9. Exposure Reduction as an Benefit Category

Charge Question 3: *Should reduction/elimination of **exposure** be evaluated as a separate benefits category, in addition to or in conjunction with mortality and morbidity reduction?*

Dr. Smith noted that he did not believe there was a basis for valuing a reduction or elimination of exposure as a separate benefit category within the existing framework that has been used. He referred to his notes compiled earlier (see Attachment N) indicating that his premise was that the question involved an additional premium when a risk changes and with the assumption that the risk has already been valued for all the effects. His note evaluated two rationales, one involving psychological literature on the way different risks are viewed and one involving a premium for the prospect that one learns over time and can adjust ones behavior, but that for some decisions an irreversible condition might occur that preclude one from changing the outcome on the basis of this learning. He concluded for both that such premiums were unneeded.

Other Panel Comments:

- Double counting would exist if one counted exposure reduction as a benefit in cases where risk analysis has accounted for all the health outcomes that are realistic, but it would not be in cases where risk analysis excluded some of the risks and many of the arsenic "effects" fall into this area.

– This is really about accounting for anxiety and fear. Is there a regulatory level at which this would not exist (1, 3, 10) - some omnibus protection against the known and the unknown?

– If one could obtain good measures of what people do to reduce their risk based on their clear understanding of the medical treatment issues, etc. then that should be built in – clearly there is a risk aversion component.

– The construct of SDWA poses an MCLG at one level that is usually lower than the MCL selected. With an MCLG of zero, setting the MCL above zero says to some that they are not safe from the effect.

10. Public Comments

The Chair recognized members of the public that had preregistered for comment and one other that had this day noted a desire to speak. NOTE: A later retrieved telephone call added a public commenter who requested time for the next day because he could not be available on day one (NRDC representative). The following comments were made.

A. Association of Metropolitan Water Agencies, Mr. Jeff Mosher (4:21 pm - 4:30 pm)

Mr. Mosher's public comment is included as Attachment O. His comments apply to all drinking water standard development activities, not just arsenic. He: discussed the need to meet the cost-benefit provisions of the Act; concluded that EPA's analyses stray from accepted cost-benefit practices and tend to only discount costs not benefits; noted EPA's omission of latency periods in the analysis; disagreed with EPA's decision that QALYs are not well-established; and noted that their analytical procedures obscure benefits and costs at the community level.

B. T. David Chinn, American Water Works Association

Mr. Chinn's public comment is included as Attachment P. His comments extend to all drinking water regulations, not just arsenic. He noted a concern that the EPA methodology overestimates benefits and underestimates costs and leads to artificially low standards. He called for refinements in its benefit-cost methodology, discussed latency, called for informed judgement in estimating unquantified benefits, and encouraged EPA to include alternative benefit - cost tools (e.g., regrets analyses) to get multiple measures.

C. Kevin L. Bromberg, Assistant Chief Counsel for Environmental Policy, U.S. Small Business Administration

Mr. Bromberg stated that he had worked with EPA and OMB on the rule. He stated that the 10 ppb standard is not justified under the provisions of SDWA. His basic issues was characterized as the uncertainty of the health effects of arsenic and EPA's narrow treatment of risk and uncertainty. He noted comments from the NRC in support of his statement.

D. Eric Olsen (8:52 to 9:02 am on Friday) (Chronologically, this occurred on day 2. The speaker could not be available on day 1 and called in on that day to request time on the agenda for the following day. His comments are captured her for continuity in the minutes).

Mr. Olsen's public comment, and referenced material, is included as Attachment Q1 through

Q4. In his comment, he stated that: SAB should recommend EPA estimate cancer risk consistent with NRC key findings; EPA's cancer risks are lower than NAS and others; putting dollar values on lives lost is questionable; EPA should quantify all non-cancer health effects if it uses dollar valuations; EPA assumes a low value for human life; discounting is unjustified; and EPA ignores medical costs, horror, dread, and pain of cancer.

Adjourned for the Day (4:45 pm)

Friday July 20, 2001

8:30 am **Reconvene** Dr. Cropper, Chair

11. Issues in Characterizing Costs

Dr. Freeman noted that in considering the welfare implications of costs, what matters is how much it costs and what is passed on to consumers and water systems. For that, the discount rate used to amortize capital costs and which is built into the rate system is what matters (or the taxes paid if costs come from taxes). There is no reason to believe that that rate is either 3% or 7% as used in EPA's analysis. A figure between 4.55 and 5.5% can be obtained from information in Chapter 6 of the agency analysis. An addition to the discussion noted that the rates presented should be realistic and to be realistic, one has to look at whether the utility is investor owned or municipal and factor in their actual cost of capital that may differ because of their revenue sources.

EPA Comments:

– EPA representatives noted that the 3% and 7% are contained in the economic analysis guidelines and that the different rates in Chapter 6 were weighted to reflect that some smaller utilities obtain grants or low cost loans to help with costs

12. Total vs. Incremental Costs and Benefits

Charge Question 4: *How should total benefits and costs and incremental benefits and costs be addressed in analyzing regulatory alternatives to ensure appropriate consideration by decision makers and the public?*

Dr. Hanemann started by stating that the cost analysis itself is aggregated and cautionary and he did not think it to be a reliable estimate of cost (See attachment R). He suggested the analysis focus on the subset of utilities affected by the regulation. He noted the great heterogeneity in water systems in terms of contaminant concentrations, sources of water, prices, treatment in place, treatment needed to respond to the rule, etc., all of which are not factored into the analysis. Without considering these elements one could have inflated cost estimates. He suggested that benefits, costs and net benefits be calculated as much as possible on a utility by utility (system by system) basis except for the smallest ones and there one might need to do the analysis on averages. Then one could report the benefit-cost ratios (>2, >1.5, >1.0, etc.) by system size. Though ratios are included in Exhibit E problems in the cost analysis make the net benefit calculation unreliable. One could also consider nonstructural responses to the rule (e.g., source switching, new well, delivery of bottled water). Dual water systems for potable vs. non-potable use are under discussion in some utilities now even though SDWA does not allow EPA to require such an option. The argument is not for a conclusion but rather conducting the analysis so you have additional information on the tradeoffs. Monte Carlo simulation does not substitute for a more fine grained analysis tailored to some of the more major utilities that are involved. The issue of affordability and the percent of a system's water which goes to industrial facilities vs. residential use

was discussed. In the former situation if the cost to households is too high a response that reduces total water use might be the outcome and that could impact the financial health of the utility. These could be considered for some financial support. `In the latter, the cost of treatment is born by customers and not by residents.

In summary, aggregation distorts and produces unreliable estimates. You can't say if it raise or lowers the estimates but it makes them unreliable. In principle it is appropriate to ask about the extra benefit you get in going from one standard to another and as a goal selecting the point at which you maximize net benefits. That assumes you are comprehensive in covering the benefits (effects) that are reasonable. At least the analysis is informative if not directive.

Other Panelist Comments:

- What is suggested is a complete sample of the large cases and a stratified sample of the small ones.

- With respect to incremental costs and benefits, the point is that if you do not have a good basis for developing the cost estimates then there is no basis for understanding what the cost increment from one standard to another might be. Without better detail in the cost analysis, the incremental benefit - cost information is not useful.

EPA Comments:

- Though the analysis did consider in some way some of the issues noted by Dr. Hanemann, data to permit quantitation of cooccurrence and cocontrol is too limited.

- Some utilities are talking about dual systems (bottled water) because of the loss of public support for their systems due to contamination concerns and not so much as a response to cost issues.

- One of the difficulties is that EPA does not know which water systems are in the 3500 systems that will need to take action.

- The NDWAC Cost work group may be looking at point of use/point of entry devices in their new analysis and they may be discussing different standards for different system sizes, though states do not want to be in the position of saying that systems that can afford more protection should do so and those that can't afford it get less protection.

Break

13. Incorporation of Uncertainty into Benefits Measures (10:15 am)

> **Charge Question 5:** *How should uncertainties be addressed in the analysis to ensure appropriate consideration by decision makers and the public?*

Dr. Hattis noted that uncertainty causes great anxiety for technical people and users of their analyses. One problem is that it is often viewed as a threat to the information and analysis. A second problem is that uncertainty analysis is often done as an afterthought and done badly. Even so, uncertainty analysis should be encouraged, allowed, and moved from a peripheral issue to center stage because it is a prime input to communication among those responsible for decision making and broad groups of the public. With uncertainty information users also have a better position from which to judge

alternative control strategies.

Dr. Hattis also discussed a number of issues with uncertainty analysis, including: 1) its link to policy development; 2) how it can help one understand inequities by looking at the variability among people and systems; 3) its ability to help one understand what a mean is telling us; 4) how uncertainty analysis can help explain how realistic input from disparate disciplines might be–what counts as an acceptable amount of information in the discipline; 5) validity (measures what you say it does) versus reliability (reasonable, acceptable, reproducible); and 6) relevance of the assessment to policy analysis;

Dr. Hattis discussed uncertainty and variability in the drinking water causal chaing between consumption and occurrence of effects. This included uncertainty and/or variability in: 1) occurrence assessment, 2) measurement of arsenic, 3) dose response and susceptibility of various persons due to age, genetic makeup, preexisting conditions, among others; and 4) selection of points of departure and use/nonuse of comparison populations in the Morales analysis.

Dr. Smith suggested some advice that could be given and noted a preference for beginning with the articulation of some general principles for dealing with uncertainty and then going to specific suggestions on how the analysis might be supplemented. He noted a number of general points to make: 1) be transparent and specifically identify which components of the analysis were subjected to uncertainty evaluation and which components recognized variability (simple table noting elements of the analysis, what assumptions were used, which elements we introduced a recognition of heterogeneity into the analysis at least); 2) look at the structure of the analysis for both benefits and costs and reflect the implications of uncertainty and variability on benefits and costs at a system level; and 3) evaluate whether adding the various endpoints seems reasonable in the real world for persons and consider both whether the affordability analysis is reflective of the real world and whether people would pay a certain amount to avoid the various effects we say are possible (see Attachment S).

Other Panelist Comments:

- Differences between study populations and populations to which that data are applied in risk assessments can be important considerations.
- Variability matters when separate items are correlated and not independent. This is relevant to the need to look at net benefits at a systems level.
- The Morales paper shows that probability of getting cancer varies with age (big time). The EPA document does not discuss the age-dependence of these risks.
- For the charge, a list of uncertainties and practical advice on how they should be incorporated into the analysis would be helpful in answering the charge question.
- In addition to uncertainty and variability one needs to know which factors were omitted from the analysis because they were uncertain (one group is the unquantified health effects).
- A recommendation to do sensitivity analysis on some different models and presenting the results could be helpful.
- Implications of flat distributions vs. normal and log normal distributions and their simplicity or lack thereof.

- Is it necessary to consider arsenic's synergistic relationships (e.g., lung cancer and smoking vs. arsenic)?

- One should not give the false impression by talking about upper and lower bounds that you have considered multiple uncertainties, especially when the two cases differ in only one parameter–probably need to do sensitivity analyses for different models. These are not bounds.

- Be honest about what is and is not in the analysis and whether the uncertainty from each element is large or small in relation to the bottom line. At least articulate what has been done.

- Breaking the total analysis down into small, medium, and large sized systems and looking at uncertainty in the risk component as well as the economic component allows one to look for intermediate courses of action instead of the all or nothing situation that is now reflected in the aggregate analysis done by EPA. One can capture things as defined sets of percentiles as opposed to the extreme values.

- Part of the problem in understanding EPA's discussion of uncertainty/variability is that information on what it has done is scattered throughout a number of documents. Because part of the question asks how to communicate/present information to decision makers and the public, a summary treatment of the issue can make the level of confidence in the various estimates more transparent and clear. Transparency empowers those receiving the information and it can build confidence in the process and the outcome.

Comments from Observers:

- Mr. Laity (OMB) wondered how an uncertainty analysis that was as broad as say zero to $4 billion for a benefit could be used by decision makers. He stated that EPA had done a good job of documenting in excruciating detail (FRN and appendices of economic analysis) what went into their judgments and he was not certain how the advice of the Panel differed from what they have now done.

14. Main Points for the Cover Letter

Dr. Cropper asked Panelists to articulate the important points that should be emphasized for the Administrator. Some of the recommendations were made as we discussed each charge question over the course of the meeting. Dr. Hanemann made the following suggestions regarding Charge question 4 on comparing benefits (other Panelists comments are also noted). The recommendation for this charge should emphasize: 1) EPA should conduct the analysis on the subset of utilities affected specifically incorporating information about them; it should combine the benefits and costs on a system basis; and present the analysis on a systems basis. Also, EPA should include the number of utilities facing costs exceeding current revenue – broken down to show these incrementally for the optional MCLs being considered rather than in the aggregate.

In response to a question on use of QALYs as a way to provide additional information beyond monetization) Dr. Hanemann noted that it is appropriate to present health outcomes in physical terms (like number of cases of death, morbidity, etc., as summary measures) Even QALYs could help inform decision makers better than simply listing the effects. Dr. Smith dissented from using QALYs as a summary measure because they are so different from the normal benefit-cost numbers used that they

could confuse the issue.

Other Panelist Comments:

– Include cost of illness, and loss of utility/productivity.

– As an option to using the chronic bronchitis number that all Panelists seem to dislike, one might consider some unquantified health endpoints relative to other endpoints that are already valued in the literature. This needs to be presented as a judgment call and would require very credible and strong evidence on the differences in the conditions being compared.. NOTE: Dr. Smith dissented from this unless there was an empirical basis for making the judgment. Dr. Freeman noted lessened concern because the advice ultimately is only one of many inputs to decision making and it is intended to better inform than what one gets with a mere list of effects. Dr. Hattis noted that it is inappropriate to assume that because some effects can't be quantified for lack of an empirical basis, that they do not have value. Dr. Cropper noted that the issues are public health issues and involve real money as well and without an empirical basis one could give misleading information. There are only a few studies out there on this issue. In sum, in support of the transparency notion, there could be included in the analysis, the list of unquantified endpoints, the number of studies showing a concern, a benchmark dose/odds ratios/etc., a measure of variability, possibly some indication of the relative strength of the effect relative to some other estimated effect, a reference dose. A final list was not specified.

Lunch

15. Next Steps (1:15 pm)

A. Schedule:

1. Writing assignments to Dr. Cropper and Mr. Miller by Tuesday, July 31, 2001

2. Prepare a draft for circulation to the Panel; August 3

3. Comments from Panel; August 8

4. Draft to Panel, Public, EC; August 10

5. Teleconference to discuss any continuing issues and reach closure on the report, Tuesday, August 14

6. Revise report as Panel consensus; Friday August 17

7. SAB Executive Committee review of the Panel Report; TBD but likely week of August 27

8. Revisions and final report to the Administrator; Friday, August 31, 2001.

B. Writing Assignments

1. Charge Question 1 (Health--Latency). Dr. Bull, with Freeman and Hattis inputs

2. Charge Question 2 (Health–Nonquantified Effects). Dr. Hertz-Picciotto with Bull and Hattis inputs

3. Charge Question 2 (Economics–Nonquantified Effects). Dr. Freeman

4. Charge Question 3 (Exposure as a benefit category). Dr. Smith

5. Charge Question 4 (Incremental vs Total Benefits and Costs): Dr. Hanemann

6. Charge Question 5 (Uncertainty) Dr. Hattis on risk and Dr. Smith on Benefits

7. Cover Letter to the Administrator: Dr. Cropper

C. Outline of the report

The general outline of the report will follow this approach:

Cover letter
Background and context of the rule and review
General comments of the Panel
Specific comments of the Panel on the Charge Questions:
1 ...
2 ...
3 ...
4 ...
5 ...

(The general format should address what EPA did in its analysis, its reasonableness and appropriateness, the advice on the question from this Panel, and reference to the NDWAC and NRC panels on cost and health updates as appropriate. Because EPA will want to extend the advice beyond the arsenic case, any limitations in that regard to the advice should be considered for addition to the report.)
References, etc.

In closing Dr. Cropper thanked the Panelists. Mr. Miller cautioned the Panelists to be careful about those from the outside contacting them outside the process to lobby for specific points of view in the report.

3:07 pm **Adjourn the Meeting**

The Chair adjourned the meeting.

I certify that these minutes are accurate to the best of my knowledge.

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_____	_____
August 20, 2001	
Dr. Maureen Cropper	Mr. Thomas O. Miller
Chair	Designated Federal Officer
Arsenic Rule Benefits Review Panel	Arsenic Rule Benefits Review Panel

Attachments:

A **FR 66(127), pp. 34924-34928, 7/2/01**
B **Agenda**
C **Panel Roster**
D **Sign-in Sheets**
E **Charge to the Panel from EPA**
F **Statement by Dr. Bull on his clients**
G **Letter from the Administrator**
H **Overheads of Mr. Ephraim King**
I **Mr. Letkiewitz's overhead**
J **Estimated Per Capita Water Ingestion in the United States"**
K **Dr. Bull's system size analysis**
L **Arsenic occurrence report**
M **Table of Effects; Dr. Hertz-Picciotto**
N **Dr. Smith's notes on exposure as a benefit**
O **Statement of Mr. Mosher, AMWA**
P **Statement of Mr. Chinn, AWWA**
Q **Statement and background information from Mr. Olsen**
R **Dr. Hanemann's notes**
S **Dr. Smith's notes on uncertainty analysis**

Attachment B

U.S. Environmental Protection Agency
Science Advisory Board
Executive Committee
Arsenic Rule Benefits Review Panel*

CHAIR

Dr. Maureen L. Cropper, Lead Economist, The World Bank, Washington, DC
Also Member: Advisory Council on Clean Air Compliance Analysis

OTHER SAB MEMBERS

Dr. Richard Bull, Consulting Toxicologist, MoBull Consulting, Kennewick, WA
Member: Research Strategies Advisory Committee
Drinking Water Committee

Dr. W. Michael Hanemann, Professor, University of California, Berkeley, CA
Member: Environmental Economics Advisory Committee

Dr. V. Kerry Smith, University Distinguished Professor, Department of Agricultural and Resource Economics, North Carolina State University, Raleigh, NC
Member: Advisory Council on Clean Air Compliance Analysis

CONSULTANTS

Dr. A. Myrick Freeman, Professor, Department of Economics, Bowdoin College, Brunswick, ME

Dr. Dale Hattis, Research Associate Professor, Center for Technology, Environment, and Development (CENTED), Clark University, Worcester, MA

Dr. Irva Hertz-Picciotto, Professor, Department of Epidemiology, University of North Carolina, Chapel Hill, NC.

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Attachment E

ELECTRONIC VERSION: Signed June 8, 2001

MEMORANDUM

To: Donald Barnes, Director
Office of the Science Advisory Board (SAB)

From: Diane Regas / S /
Acting Assistant Administrator (OW)

Subject: Request for Review of the Benefits Assessment for the Arsenic in Drinking Water Regulation

With this memo, EPA is requesting the Science Advisory Board (SAB) to perform a review of the benefits analysis prepared by EPA in support of the arsenic drinking water standard. The Agency requests the SAB to review the benefits assessment component of the regulatory support document entitled *Arsenic in Drinking Water Rule Economic Analysis* (EPA 815-R-00-26, 2001). The document provides a detailed assessment of the quantified and unquantified costs and benefits of the arsenic rule, as required by the Safe Drinking Water Act (SDWA). EPA would like a report of findings and recommendations that answer the five questions posed in the attached Scope of Review. Also attached are other pertinent documents that will be of interest to the SAB in conducting the review: (1) the preamble to the January 22, 2001 arsenic rule *(66 Federal Register 6976*); (2) *EPA Guidelines for Preparing Economic Analyses* (EPA-240-R-00-003, September 2000); (3) the *Report of the Benefits Working Group of the National Drinking Water Advisory Council* (unpublished, October 1998); and (4) SAB's July 2000 Report on EPA's White Paper, *Valuing the Benefits of Fatal Cancer Risk Reduction*.

In order to ensure that SAB's recommendations are fully considered in decision-making, it is important that the review be made available to the Administrator by August 2001 to coincide with the findings and recommendations from independent reviews of the health effects by the National Academy of Sciences and costs by the National Drinking Water Advisory Council.

Background

Studies have linked long-term exposure to arsenic in drinking water to cancer of the bladder, lungs, skin, kidney, nasal passages, liver, and prostate. Non-cancer effects of ingesting arsenic include cardiovascular, pulmonary, immunological, neurological, and endocrine (e.g., diabetes). The current standard of 50 ppb was set by EPA in 1975, based on a Public Health Service standard originally established in 1942. A March 1999 report by the National Academy of Sciences concluded that the current standard does not achieve EPA's goal of protecting public health and should be lowered as soon as possible.

The SDWA requires EPA to revise the existing 50 parts per billion (ppb) arsenic standard. In response to this mandate, the Agency published a standard of 10 ppb to protect consumers against the effects of long-term, chronic exposure to arsenic in drinking water on January 22, 2001. The rule is significant in that it is the second drinking water regulation for which EPA has used the discretionary authority under §1412(b)(6) of the SDWA to set the Maximum Contaminant Level (MCL) higher than

the technically feasible level, which is 3 ppb for arsenic -- based on a determination that the costs would not justify the benefits at this level. The January 22, 2001 arsenic rule is based on the conclusion that a 10 ppb MCL maximizes health risk reduction at a cost justified by the benefits.

Key stakeholder concerns on the benefits component of the economic analysis include the following issues: (1) the timing of health benefits accrual (latency); (2) the use of the Value of Statistical Life as a measure of health benefits; (3) the use of alternative methodologies for benefits estimation; (4) how the Agency considered non-quantifiable benefits in its regulatory decision-making process; (5) the analysis of incremental costs and benefits; and (6) the Agency's assumption that health risk reduction benefits will begin to accrue at the same time costs begin to accrue.

The January 22, 2001 rule will apply to all 54,000 community water systems and requires compliance by 2006. A community water system is a system that serves 15 locations or 25 residents year-round, and includes most cities and towns, apartments, and mobile home parks with their own water supplies. EPA estimates that roughly five percent, or 3000, of community water systems, serving 11 million people, will have to take corrective action to lower the current levels of arsenic in their drinking water. The new standard will also apply to 20,000 "non-community" water systems that serve at least 25 of the same people more than six months of the year, such as schools, churches, nursing homes, and factories. EPA estimates that five percent, or 1,100, of these water systems, serving approximately 2 million people, will need to take measures to comply with the January 22, 2001 rule. Of all of the affected systems, 97 percent are small systems that serve fewer than 10,000 people each.

Attachments

cc: Tom Gibson, OPEI
Al McGartland, OPEI
Cynthia Dougherty, OGWDW
Ephraim King, OGWDW

June 2001

ARSENIC BENEFITS PANEL: SCOPE OF REVIEW

The panel will review quantified and unquantified arsenic benefits analysis as required by SDWA, and evaluate whether the components, methodology, criteria and estimates reflected in EPA's benefits analysis are reasonable and appropriate in light of the Science Advisory Board's (SAB) benefits transfer report, EPA's Guidelines for Preparing Economic Analyses (September 2000) developed in consultation with SAB, relevant requirements of SDWA, National Drinking Water Advisory Council recommendations to EPA on benefits, and recent literature. As part of a general review, consideration should be given to the following issues:

a) How should total benefits and costs and incremental benefits and costs be addressed in analyzing regulatory alternatives to ensure appropriate consideration by decision makers and the public?

b) How should latency be addressed in the benefits estimates when existing literature does not provide specific quantitative estimates of latency periods associated with exposure to arsenic in drinking water?

c) Should reduction/elimination of exposure be evaluated as a separate benefits category, in addition to or in conjunction with mortality and morbidity reduction?

d) How should health endpoints (other than bladder and lung cancer) be addressed in the analysis, when [existing] literature does not provide specific quantification, to ensure appropriate consideration by decision makers and the public?

e) How should uncertainties be addressed in the analysis to ensure appropriate consideration by decision makers and the public?